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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,110	08/10/2001	Bing Zhu	MBM1240	3840

7590 06/18/2003

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EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	12

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/27/03

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-8, 15, 16, 20-22, 48-57 is/are pending in the application.
Of the above, claim(s) ~~48-57~~ 48, 49, 51, 52 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1, 3-8, 20-22, 50, 53-57 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1, 3-8, 15, 16, 20-22, 48-57 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☒ The drawing(s) filed on 8/10/01 is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1996-404-496/40517

Part III: Detailed Office Acti n

Restriction Requirement:

Applicant's election with traverse of invention I with an election of species of MS in Paper No. 11, filed 3/27/03 is acknowledged. The traversal is on the ground(s) that (1)the groups of inventions are not independent, and (2) the examination of the entire application would not constitute a burden to search. This is not found persuasive because with respect to point (1) above, the inventions are distinct as noted in the last Office Action, as shown by the distinctness described therein. Applicant's attention is directed to MPEP 806.05. With respect to point (2) above, contrary to applicants' assertion that any search of the prior art in regard to group I will reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3-8, 15, 16, 20-22, 50 and 53-57 are under consideration.

Formal Matters:

The drawings are objected to because the poor photocopy quality does not allow visualization of the details discussed in the brief description of Figures 1, 3, 4, 9 and 11. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The disclosure is objected to because of the following informalities:

The brief description of the drawings should be amended to refer to each separately numbered figure, e.g. Figures 1A and 1B. See §37 CFR 1.74.

Appropriate correction is required.

Applicant is advised that should claims 20-22, 50 and 53-57 be found allowable, claims 1, 3-8, 15 and 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6-8, 15, 16, 20-22, 50 and 55-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The specification and claims are drawn to the use of a Fas ligand for modulating inflammation. Fas ligand is known in the art, as are soluble fragments of such. However, the claims broadly read on the use of not only Fas ligand and fragments thereof, but also on unspecified "derivative thereof". The specification discloses "derivatives" as encompassing any and all amino

acid substitutions deletions or insertions in FasL, any possible type of chemical modification, and even peptidomimetics or peptide analogues (page 17), which are not required to have any structural similarity, but merely functional equivalence to Fas L. The written description does not support such breadth, nor is there sufficient guidance nor working examples to support such breadth. Accordingly, enablement is not commensurate in scope with the claims.

It was found in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

> Appellants have not chosen to claim the DNA by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt*, 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

In this case, applicants claims resemble those of Maizel in that they are claiming a method of using any product that will be effective in that method, whereas the only means disclosed is FasL or fragments thereof.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 15, 16, 20-22, 50, and 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellgrau et al., WO 95/32627, cited by applicants.

Bellgrau et al. teach methods of using FAS ligand to suppress lymphocyte mediated immune responses, including inflammation (see claim 20). Use of soluble FAS ligand is disclosed at page 11, and treatment of MS is specifically disclosed at page 14. As MS is a disease of the CNS, the person of ordinary skill in the art reading the disclosure of Bellgrau et al. would immediately grasp that the administration for treatment of MS would be to the CNS, meeting the limitation of "behind the blood-tissue barrier of the immune privileged site". Accordingly, the claims, taken as a whole, are anticipated by the disclosure of Bellgrau et al.

Claims 1, 3-8, 15, 16, 20-22, 50, and 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Queen et al., U.S. Patent Number 6,046,310, cited by applicants.

Queen et al. teach methods of using FAS ligand fusion proteins to treat autoimmune diseases, including MS; see column 5 lines 38-45 and column 9, at lines 15-20. As MS is a disease of the CNS, the person of ordinary skill in the art reading the disclosure of Queen et al. would immediately grasp that the administration for treatment of MS would be to the CNS, meeting the limitation of "behind the blood-tissue barrier of the immune privileged site". Accordingly, the claims, taken as a whole, are anticipated by the disclosure of Queen et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Number 6,042,826, cited by applicants, discloses direct administration of soluble

Fas-L to the CNS for the treatment of lymphoma, see col. 4 lines 13-24.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 5:00 A.M. to 9:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Lorraine Spector, Ph.D.
Primary Examiner

09/927110.1
6/12/03